

EXHIBIT M

Konstantin Walmsley, M.D.

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE ETHICON, INC., PELVIC :Master File NO.
REPAIR SYSTEM PRODUCTS :2:12-MD-02327
LIABILITY LITIGATION :
:MDL 2327

THIS DOCUMENT RELATES TO THE :
FOLLOWING CASE IN WAVE 2 OF :
MDL 200 :

HOPE ELAINE PRIDMORE, :
:JOSEPH R. GOODWIN
Plaintiffs, :U.S. DISTRICT JUDGE
v. :
:ETHICON, INC., et al., :
:Case No.
Defendants. :2:12-CV-02190

June 6, 2016

Oral sworn videotaped deposition of
KONSTANTIN WALMSLEY, M.D., held at COURTYARD
MARRIOTT WEST ORANGE, 8 Rooney Circle, West
Orange, New Jersey, before Margaret M. Reihl,
RPR, CCR, CRR, CLR and Notary Public, on the
above date, commencing at 1:32 p.m., there
being present:

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Konstantin Walmsley, M.D.

1	I N D E X		
2	WITNESS:		Page
3	KONSTANTIN WALMSLEY, M.D.		
4	By Mr. Moriarty		5, 93
	By Mr. Thompson		91

--

6	E X H I B I T S		
7	WALMSLEY-BAILEY DEPOSITION EXHIBITS		MARKED
8			
9	No. 1	Curriculum Vitae Dr. Walmsley	5
10	No. 2	Urinary Incontinence Treatment	
11		document, "Urinary Incontinence	
12		Treatment in New Jersey"	23
13	No. 3	Document, "Risks Associated With	
		Any Pelvic Floor Surgery"	37
14	No. 4	Pamphlet, "Find out how to stop	
15		urine leakage like Bonnie did"	40
16	No. 5	Surgeon's Resource Monograph,	
17		"Expert opinions on the use of	
18		Gynecare TVT Tension-Free Support	
19		for Incontinence"	
20		[ETH.MESH.10027307 through 10027328]	41
21	No. 6	Pamphlet, "Gynecare TVT Obturator	
22		System"	
23		[ETH.MESH.02340974 through 02340980]	66
24	No. 7	Medical records for Hope Pridmore	
		from Howard Diamond, M.D.	
		[PRIDMOREH_HDIAM_MDR00001 through	
		00061]	47
	No. 8	St. Margaret Mercy History and	
		Physical, admitted 8/1/07	
		[PRIDMOREH_FRANSTMH_MDR00632	
		through 00633]	58

Konstantin Walmsley, M.D.

1	No. 9	Community Healthcare System Emergency Department record dated	
2		11/17/11	
3		[PRIDMOREH_COMHO_MDR00394	
4	No. 10	through 00397]	63
5		Community Healthcare System	
6		Inpatient record dated 11/19/11	
7		[PRIDMOREH_COMHO_MDR00411	
8	No. 11	through 00413]	63
9		St. Margaret Mercy record	
10		by Dr. Zaidi	
11		[PRIDMOREH_FRANSTMH_MDR00443	
12	No. 12	through 00444]	66
13		Community Healthcare System	
14		Inpatient record dated 12/4/13	
15		[PRIDMOREH_COMHO_MDR01015]	66
16	No. 13	Community Healthcare System	
17		Urinalysis Dipstick record dated	
18		7/15/15	
19		[PRIDMOREH_COMCAN_MDR00008	
20	No. 14	through 00052]	67
21		Community Healthcare System	
22		H&P record dated 10/1/15	
23		[PRIDMOREH_SMAMC_MDR00005	
24	No. 15	through 00071]	73
25		Medical Specialists Centers of	
26		Indiana record dated 4/12/12	
27		[PRIDMOREH_MUMEC_MDR00039	
28	No. 16	through 00042]	78
29		Medical Specialists Centers of	
30		Indiana record dated 9/27/12	
31		[PRIDMOREH_FMS_MDR00009	
32	No. 17	through 00015]	79
33		Operative notes, admit date	
34		11/18/13	
35		[PRIDMOREH_FRANSTMH_MDR02612	
36		through 02614]	80
37		— — —	

1 ... KONSTANTIN WALMSLEY, M.D., having
2 been duly sworn as a witness, was examined and
3 testified as follows ...

4 BY MR. MORIARITY:

5 Q. Tell us your full name.

6 A. Konstantin Walmsley.

7 Q. Dr. Walmsley, you've been deposed before
8 in other cases; have you not?

9 A. I have.

10 Q. I'm sure you've heard these rules a
11 dozen times, if you don't understand my question, you
12 tell me, okay?

13 A. Okay.

14 Q. And you have to keep your answers out
15 loud and in plain English so that Peg can understand
16 and take them down, okay?

17 A. Yes, sir.

18 (Document marked for identification as
19 Walmsley Pridmore Deposition Exhibit No. 1.)

20 BY MR. MORIARITY:

21 Q. Handed you Exhibit 1.

22 Is that your CV?

23 A. It is.

24 Q. Have you ever made a presentation at a

1 medical conference about stress urinary incontinence?

2 A. I have offered grand rounds
3 presentations in the past, if that answers your
4 question.

5 Q. Grand rounds would be internal to your
6 hospital system?

7 A. Yes.

8 Q. Okay. But not at a CME conference,
9 where it's just all, you know, physicians and you're at
10 an independent location and it's for CME credits and
11 that sort of thing?

12 A. I have not.

13 Q. All right. Have you made a presentation
14 at a medical conference about synthetic midurethral
15 slings?

16 A. I have not.

17 Q. What about autologous fascial slings?

18 A. I have not.

19 Q. Have you published anything in the peer
20 reviewed medical literature about stress urinary
21 incontinence?

22 A. I have not.

23 Q. Have you published anything in the peer
24 reviewed medical literature about synthetic midurethral

1 slings?

2 A. I have not.

3 Q. What about autologous fascial slings?

4 A. I have not.

5 Q. Are autologous fascial slings a category
6 of pubovaginal slings?

7 A. That's correct.

8 Q. Could I use those interchangeably and we
9 would still be communicating clearly today?

10 A. Yes, you may.

11 Q. Do you know how much you have billed to
12 date on the Pridmore case, which is the case I'm here
13 to ask you about?

14 A. Yes, I do.

15 Q. And do you have paper to that effect, a
16 bill, a ledger?

17 A. I have an invoice that I've submitted
18 that I have electronically with me today that's on the
19 order -- if that was going to be your next question --
20 of between 4 and \$6,000, I believe.

21 Q. All right. Just on the Pridmore case?

22 A. Yes, sir.

23 Q. And that would be through when?

24 A. Certainly through today. I have not

1 obviously billed for today. That would be through the
2 early portion of May.

3 Q. So, for example, if you add prep time
4 with Mr. Thompson or any other lawyer to get ready for
5 today, that has not yet been billed?

6 A. That's correct.

7 Q. All right. Do you have any estimate of
8 how much time that has been since early May that you've
9 worked on the Pridmore case separately?

10 A. Probably between about two and three
11 hours, yes.

12 Q. And do you know a total of how much you
13 have been paid or how much you have been billed overall
14 for all of your mesh consulting with plaintiffs'
15 lawyers?

16 A. I have been paid about between about 40
17 and \$50,000 to date for this work.

18 Q. And there's some, I presume, invoiced
19 not yet paid?

20 A. I believe so. Well, I shouldn't say I
21 believe so. Yes, that number is a little more
22 nebulous, but this is true.

23 Q. Now, I am sorry if I'm covering a topic
24 that was covered last Friday, but you have some

1 opinions in your report in this case, and do you have
2 your report in the Pridmore case?

3 A. I do.

4 Q. Have you ever participated in writing an
5 instructions for use for a medical device?

6 A. I have not.

7 Q. Do you consider yourself to be an expert
8 in the FDA regs or guidance documents regarding IFUs?

9 A. I would not offer that opinion, no.

10 Q. Have you ever read the FDA regs or
11 guidance documents that generally describe what's
12 supposed to be in an IFU?

13 A. I have perused them.

14 Q. Had you ever perused those regs before
15 you were retained as an expert in mesh litigation?

16 A. No.

17 Q. Have you ever held yourself out to
18 anyone in the medical or scientific community as an
19 expert in warnings for medical devices?

20 A. No.

21 Q. Now, I understand you take care of men
22 and women, correct?

23 A. I do.

24 Q. And what is the percentage of your

1 practice that is male patients?

2 A. Roughly two-thirds to 70%.

3 Q. And of those male patients, how many do
4 you treat for SUI?

5 A. Probably in the order of 2%.

6 Q. And I assume those are mostly post
7 prostatectomy patients?

8 A. That's correct.

9 Q. Oh, by the way --

10 MR. MORIARTY: Off the record.

11 (Discussion off the record.)

12 BY MR. MORIARTY:

13 Q. So 25 to 30% of your practice is
14 females, correct, and of that group of patients, what
15 percentage of those have SUI, even if they also have
16 POP?

17 A. I would estimate between 10 and 20%,
18 perhaps more on the 10% side of things.

19 Q. Do you take care of women for pelvic
20 organ prolapse?

21 A. I do.

22 Q. So that 10 to 20% of your female patient
23 population could be pure SUI with no POP or it could be
24 concomitant disease, correct?

1 A. That's correct.

2 Q. And then I want to make sure I
3 understand the procedures that you do.

4 Obviously, you -- and I'm just going to
5 talk about procedures for SUI in women. You do -- you
6 perform autologous fascial sling procedures; do you
7 not?

8 A. Yes.

9 Q. Do you know how many you have performed
10 overall or about how many per year you perform?

11 A. Including my training?

12 Q. Yes, sir.

13 A. Probably between 60 and 90.

14 Q. Per year?

15 A. No, no, not per year. Per year it's
16 less than that. It's probably on the order of single
17 digit numbers.

18 Q. So you've done 60 to 90 total autologous
19 fascial slings for SUI in women in your career?

20 A. That's correct.

21 Q. Okay. And at one point I know you were
22 doing more synthetic midurethral slings earlier in your
23 career, and now do you do about 20 a year?

24 A. That's roughly correct, yes.

1 Q. So that total number, the total number
2 performed is higher than your autologous fascial sling
3 number?

4 A. This is true.

5 Q. All right. And now I've seen some
6 testimony that you gave in another case about what
7 brands of synthetic midurethral slings you have used,
8 but I want to ask you about that because I think AMS
9 has stopped that portion of their business, so it may
10 have changed, okay?

11 A. Yes.

12 Q. What do you currently use in the way of
13 synthetic midurethral slings to treat women for SUI?

14 A. Currently, I use the Coloplast Aris
15 system, A-r-i-s.

16 Q. Anything else?

17 A. I have some remaining Bard Alliance
18 slings on my shelf at the hospital where I work out of,
19 and there is a single incision Coloplast system that's
20 available to me as well.

21 Q. Do you use it?

22 A. I have not yet, but I have intentions to
23 use it.

24 Q. What's that called, if you know?

1 A. It's on the tip of my tongue, but I
2 don't quite remember. It's the only one on the market
3 that Coloplast offers.

4 Q. We can come back to it.

5 A. Okay.

6 Q. Do you still perform native tissue
7 repairs for female SUI?

8 A. Semantics-wise, I'm not sure of the
9 question.

10 Q. Sure.

11 I assume you haven't done a
12 Marshall-Marchetti-Krantz in quite some time?

13 A. No.

14 Q. Do you still do Burch procedures?

15 A. I do not.

16 Q. When was the last time you did a Burch?

17 A. In my training.

18 Q. So I'm sure there are other procedures,
19 colpocleisis or some of these others, but Burch, MMK,
20 are there any other nonpubovaginal sling and
21 nonsynthetic midurethral sling procedures that you do
22 for SUI currently?

23 A. The only other one would be collagen
24 injections or similar types of bulking procedures.

1 Q. All right. Okay. When you're sitting
2 there thinking about a patient in front of you, what
3 are the factors you consider in deciding between
4 autologous fascial slings, synthetic midurethral slings
5 and bulking agents?

6 A. Well, I consider the severity of their
7 incontinence, the impact it has on their quality of
8 life, the functioning of the patient, for example,
9 sexual activity, prior surgeries that might have
10 altered the anatomy or the nature of their incontinence
11 and the degree of risk or extent of surgery that a
12 patient is willing to undergo to have her problem
13 fixed.

14 Q. Okay. Do you still use Gynemesh PS for
15 abdominal sacrocolpopexies?

16 A. I typically for those procedures now
17 that they're done primarily robotically, I refer them
18 to a colleague, and on occasion I'll assist my
19 colleague in the performance of that procedure. To my
20 knowledge, that is a fairly commonly used mesh.

21 Q. When you assist that colleague -- and is
22 this somebody in your urology group?

23 A. Not currently, but it may become so.

24 Q. When you assist that person, I take it

1 you don't necessarily know what brand of mesh he or she
2 chose or the hospital supplied?

3 A. That's correct.

4 Q. Okay.

5 MR. THOMPSON: Let me interrupt here,
6 does that need to be marked as confidential?
7 Is that like a trade secret that he may become
8 a part of your practice?

9 MR. MORIARTY: I didn't ask name.

10 MR. THOMPSON: Is that some sort of
11 sensitive thing, or is that just fine?

12 THE WITNESS: Well, I was thinking of
13 using someone in my group who's a
14 urogynecologist, so that's fair game.

15 BY MR. MORIARTY:

16 Q. All right. So do you still do abdominal
17 sacrocolpopexies?

18 A. I really don't.

19 Q. Do you teach residents or fellows?

20 A. I do participate in the education of
21 residents.

22 Q. At which teaching institution?

23 A. I do it out of Hackensack UMC
24 Mountainside Hospital and also out of my office as an

1 extension of my practice.

2 Q. And are these urology residents?

3 A. These are actually internal medicine and
4 family practice residents who are gleaning office-based
5 urology from spending time with me.

6 Q. Got it. Do you ever have any of them
7 scrub in to do surgeries?

8 A. I have had them scrub in to observe
9 surgeries.

10 Q. Have you ever had any of those residents
11 scrub in to a surgery involving a synthetic midurethral
12 sling for female SUI?

13 A. Off the top of my head, I would
14 conjecture yes. I don't quite remember specifically
15 the resident and the patient.

16 Q. That's fine.

17 A. Likely.

18 Q. You wouldn't hesitate to do that if the
19 circumstances were right, would you?

20 A. I would not hesitate, no.

21 Q. Did you see and examine Mrs. Pridmore?

22 A. I did not.

23 Q. Did you ever talk to her on the phone?

24 A. No.

1 Q. Do you believe that you can still render
2 opinions to a reasonable degree of medical probability
3 in her case, just based on depositions and medical
4 records?

5 A. I do.

6 Q. Have you been an expert in medical
7 negligence cases before?

8 A. I.e., medical malpractice?

9 Q. Yes, sir.

10 A. Yes, sir, I have.

11 Q. As for the plaintiff or defense or both?

12 A. Both.

13 Q. So you know, at least in New Jersey,
14 what the definition of standard of care is?

15 A. Yes, sir.

16 Q. And you have been involved in the
17 process of either saying that a doctor fell below the
18 standard of care or on the other side defending a
19 doctor and saying he or she did not fall below the
20 standard of care, correct?

21 A. That's correct.

22 Q. Do you understand standard of care
23 typically means what other reasonable, prudent, in your
24 case urologists would do under the same or similar

1 circumstances?

2 A. Yes.

3 Q. When Dr. Diamond put the TVT-O in
4 Ms. Pridmore, was he complying with the standard of
5 care --

6 MR. THOMPSON: Object to the form.

7 BY MR. MORIARITY:

8 Q. -- by offering and then placing that
9 device? If you need the year, I can tell you it was in
10 2007, I believe, September 2007.

11 A. Yes.

12 MR. THOMPSON: Object to the form.

13 THE WITNESS: Yes.

14 BY MR. MORIARITY:

15 Q. Is the use of TVT-O still within the
16 standard of care today?

17 A. It is.

18 Q. In the middle of your report, you have
19 a -- I wouldn't say the middle -- on Page 3 of your
20 report starts what I assume is your reliance list; is
21 that right?

22 A. Yes.

23 Q. So for the bottom of Page 3, all of Page
24 4 and about half of Page 5 is general information,

1 correct?

2 A. Yes.

3 Q. Not case specific?

4 A. I would probably group them under both,
5 as a matter of fact.

6 Q. Well, the case specific stuff, I mean,
7 her actual medical records, things of that nature begin
8 on Page 2, correct?

9 A. This is true.

10 Q. And go to say the middle of Page 3?

11 A. Yes.

12 Q. And then begins what I would call
13 general stuff about TVT and related topics, correct?

14 A. Yeah, this is true.

15 Q. Did you read any depositions in this
16 case?

17 A. I did.

18 Q. What deposition did you read in this
19 case?

20 A. Pridmore and Diamond.

21 Q. With all due respect, Dr. Diamond is
22 deceased and has not given testimony.

23 A. Excuse me. I stand corrected. It was
24 just Pridmore.

1 Q. Mrs. Pridmore has been deposed, and I
2 can't remember if her husband has as well.

3 A. I did not read his deposition.

4 Q. Okay. So just Mrs.?

5 A. Just Mrs. Pridmore.

6 Q. All right. This list, this reliance
7 list of general material, is that things that the
8 plaintiffs' lawyers supplied to you and chose, or did
9 you choose all of these items?

10 A. It's a bit of a combination of the two.

11 Q. All right. Are you a member of the AUA?

12 A. I am.

13 Q. You did not list the AUA statements,
14 position statements regarding synthetic midurethral
15 slings for SUI in your report, did you?

16 A. I did not.

17 Q. Is there any particular reason why?

18 A. Yes.

19 Q. And the reason is?

20 A. To my mind, the AUA statement is a
21 commentary provided by certain members of the AUA that
22 isn't necessarily reflective of my opinion.

23 Q. Are you done with your answer?

24 A. Yes, sir.

1 Q. Have you ever written a letter or spoken
2 publicly on the record against the AUA guidelines,
3 other than in a deposition for litigation?

4 A. I have not.

5 Q. Your report is on the letterhead of the
6 Urology Group of New Jersey, correct?

7 A. Yes, sir.

8 Q. And down the left side it has a number
9 of names. These are presumably all your partners or
10 shareholders, whatever business format you have,
11 correct?

12 A. Yes, sir.

13 Q. Is there a subset of this with a
14 separate name Urology of Montclair or something like
15 that?

16 A. Yes and no. If I can elaborate on my
17 answer.

18 Q. Please do.

19 A. The Urology Group of New Jersey is an
20 amalgamation of small groups that form into one. There
21 was a time that we were called Montclair Urology,
22 Montclair Urological Group. Then we became Montclair
23 Urology d/b/a UGNJ or Urology Group of New Jersey.

24 As it stands, we're a 20 plus strong

1 urologist group that has six or seven different pods,
2 if you will, offices that function somewhat
3 independently but under the administrative umbrella of
4 Urology Group of New Jersey with an evolving clinical
5 integration pattern, if you will.

6 Q. Okay. Among the group of urologists who
7 are listed on the first page of your report --

8 A. Yes.

9 Q. -- do at least some of them use
10 synthetic midurethral slings to treat female SUI?

11 A. Yes.

12 Q. Do some of these urologists on -- who
13 are listed on your letterhead do more female SUI
14 surgery than you do?

15 A. No, I don't believe so.

16 Q. Do you know if any of these other
17 colleagues of yours use Ethicon products for their
18 synthetic midurethral slings?

19 A. I don't know the answer to that
20 question.

21 Q. I mean, you used AMS and now primarily
22 you're using Coloplast. Is that by your choice, or is
23 that, as they say, what the hospital has available?

24 A. Perhaps more the latter and also perhaps

1 more the various companies pulling their products off
2 the shelves as well.

3 Q. So if some of these other urologists
4 with whom you're in practice operate at different
5 hospitals, you may not necessarily know what slings
6 they use?

7 A. This is true.

8 Q. Okay.

9 (Document marked for identification as
10 Walmsley Pridmore Deposition Exhibit No. 2.)

11 MR. MORIARITY: I'm going to hand you
12 Exhibit 2. I'm sorry, Fred, there's only so
13 much room in the briefcase for the airplane
14 ride.

15 BY MR. MORIARITY:

16 Q. This is a printout of various portions
17 of the website for Urology Group of New Jersey, and
18 then part of this was printouts of a website that still
19 exists for Montclair Urological Group, okay?

20 A. Yes.

21 Q. So does Montclair Urological Group still
22 exist as at least an entity?

23 A. No.

24 Q. All right. Tell me have you ever looked

1 at your own website?

2 A. I have.

3 Q. Did you have any role in the content of
4 your firm's website?

5 A. To some degree I did, yes.

6 Q. I assume -- obviously, there's a
7 biography about you. I assume you had some input in
8 that, correct?

9 A. I did.

10 Q. So far as the things like the reasons
11 why women get stress urinary incontinence or overactive
12 bladder or the treatment of that, did you have any
13 input into the content of your website for those?

14 A. Yes, sir, I did.

15 Q. So I'd like to -- I'm going to ask you
16 about a couple of specific things in here.

17 A. Okay.

18 Q. So if you just go to the second page of
19 this exhibit. Do you see the heading "How is Urinary
20 Incontinence Treated?"

21 A. I do.

22 Q. And then the last of the bullet points
23 is "surgery," correct?

24 A. Yes.

1 Q. And then it says, "multiple factors have
2 been found to be associated with urinary incontinence."

3 Do you see that sentence?

4 A. I do.

5 Q. So parity is one of them; is that right?

6 A. Yes.

7 Q. Age?

8 A. Yes.

9 Q. Menopause?

10 A. True.

11 Q. Some medications?

12 A. Yes.

13 Q. Or actually in your website it says many
14 medications, right?

15 A. Yes, sir.

16 Q. Poor overall general health?

17 A. True.

18 Q. Specifically diabetes, high blood
19 pressure, smoking, obesity and pulmonary disease have
20 all been associated with incontinence.

21 Do you see that?

22 A. Yes, amongst other things, this is true,
23 yes.

24 Q. Well, specifically in the Pridmore case,

1 she takes medications, she's menopausal, she has a
2 history of -- I'll get to how many children in a minute
3 but -- and then she's obese, has diabetes, high blood
4 pressure, a smoking history, correct?

5 A. Yes.

6 Q. Okay. So she is clearly at risk for
7 stress urinary incontinence?

8 A. Yes.

9 Q. And urge urinary incontinence?

10 A. To some degree, yes.

11 Q. And in a woman with these risk factors,
12 would she also be at increased risk for recurrence
13 following a surgery for SUI?

14 A. Yes.

15 Q. Okay. I'm going to count pages. I'd
16 like you to flip back, there's a page a couple in where
17 there's a blank towards the bottom. It again says
18 "Surgery," and it describes types of surgery?

19 A. Yes.

20 Q. It says slings there, correct?

21 A. Yes.

22 Q. Is this meant in your website to address
23 pubovaginal slings and synthetic midurethrales?

24 A. Can you repeat that question for me,

1 please.

2 Q. Sure. I mean, it just says slings. It
3 seems like it's being very general and encompasses not
4 only autologous fascial but also synthetic midurethral;
5 am I correct?

6 A. It's meant to, yes.

7 Q. And I didn't ask you this before, but
8 when you do autologous fascial slings, do you use bone
9 anchors or not?

10 A. I typically don't.

11 Q. All right. Let's keep flipping
12 through. Go past your bio.

13 Go to the first page where it has got
14 this Montclair Urological Group. Do you see these
15 bullet points on the -- I'm sorry, "Expert Care For A
16 Sensitive Problem."

17 Do you see that?

18 A. I'm here, yes.

19 Q. A couple of paragraphs down it says that
20 you were central in creating something called the New
21 Jersey Continence Center at Montclair Urological Group.

22 Do you see that?

23 A. I do.

24 Q. Does that still exist?

1 A. No, it doesn't.

2 Q. I'd like you to go to this page where it
3 says Montclair Urological Group and it has this long
4 set of bullet points.

5 A. Yes.

6 Q. At the beginning it says "Patient
7 Education Links."

8 Do you see that?

9 A. I do.

10 Q. So if we actually booted up a computer
11 and went to the website, if you click on some of these,
12 it takes you to other sites that have educational
13 materials; is that right?

14 A. That's correct.

15 Q. And there is one about urinary
16 incontinence, a link for that?

17 A. Likely, yes.

18 Q. Well, is there a bullet point for it?

19 A. I don't know if every bullet point has
20 links on it. Truth be told, I haven't really seen this
21 in a long while.

22 Q. All right. Go to the next page, and
23 there's a thing called "Support Organizations."

24 Do you see that?

1 A. I do.

2 Q. And these are additional links provided
3 and monitored by an organization called
4 Healthcommunities.com.

5 Do you see that?

6 A. I do.

7 Q. And among them is the National
8 Association for Continence and the Simon Foundation for
9 Incontinence, right?

10 A. Yes.

11 Q. Let's go back to where I've printed out
12 some of the linked material from Health Communities. I
13 know there's a lot of ads interspersed here, so it
14 makes it a little hard to follow, but I want to get to
15 this page where there's this ad on the right here.

16 Okay, you're there.

17 A. Yes.

18 Q. Right in here somewhere it should say,
19 "many women suffer from frequent UTIs."

20 Do you see that?

21 A. Yes.

22 Q. "With nearly 20 percent of women who
23 have one UTI also having a second."

24 Do you see that?

1 A. I do.

2 Q. "UTIs are the second most common cause
3 of physician visits each year, after respiratory
4 infections such as pneumonia."

5 Do you see that?

6 A. I do.

7 Q. Is it generally true?

8 A. You know, I'm not a primary care
9 physician, and since a lot of this stuff is treated at
10 the primary care level, I think this is giving an
11 overview to that end. I would have to say I would not
12 necessarily say it's untrue.

13 Q. All right. Do you see a lot of women
14 with UTIs?

15 A. I do.

16 Q. And one of the reasons that women have
17 typically more UTIs than men is that their GI tract,
18 which ends at the anus, is close to where the urinary
19 tract is in the female, correct?

20 A. That's one of the reasons, yes.

21 Q. Now, in an obese patient like
22 Mrs. Pridmore, morbidly obese patient, can they have
23 difficulty wiping after going to the bathroom such that
24 they might have a higher risk of UTI?

1 A. I think that's plausible, yes.

2 Q. Have you ever seen that referred to in
3 Mrs. Pridmore's medical records or in her deposition?

4 A. I recall that, yes.

5 Q. Okay. Next page, right at the top.
6 Next page. Sorry.

7 It says, "Perimenopausal and
8 postmenopausal women are also susceptible owing to a
9 decrease in estrogen production, which causes tissues
10 in the urinary tract to thin out and become more easily
11 inflamed."

12 Did I read that correctly?

13 A. You did.

14 Q. Do you agree with it?

15 A. I do.

16 Q. Is there a substantial medical
17 literature addressing the immunosupportive effect of
18 estrogen in the female urinary tract?

19 A. Yes.

20 Q. So if Ms. Pridmore is postmenopausal,
21 she would be -- for that reason alone, without
22 addressing other factors, she would be at some
23 increased risk of urinary tract infections?

24 A. In the absence of treatment, that's

1 true.

2 Q. Was Mrs. Pridmore also at increased risk
3 for overactive bladder syndrome?

4 A. Yes.

5 Q. Or overactive bladder? Do you call it a
6 syndrome?

7 A. It can be called a syndrome.

8 Q. Okay. I have one more thing, I think, I
9 need to ask you about in here.

10 I know it's not going to be easy for you
11 to track down, but further back in this Health
12 Communities section of the website are the links to
13 your website. There is a section about treatment for
14 SUI.

15 A. Are we in the SUI section right now?

16 MR. THOMPSON: These are numbers down in
17 the lower right?

18 MR. MORIARITY: You know what, they are,
19 but they start over and over again. So we'll
20 go one, two, three, four, five, six of six, and
21 then it will start all over.

22 THE WITNESS: Is it after the overactive
23 bladder portion?

24 BY MR. MORIARITY:

1 Q. It is, sir.

2 A. Okay. This is overactive bladder.

3 Q. Here's what this -- the page I want to
4 ask you about looks like it has these two semi-empty
5 boxes?

6 A. Oh, yes. This looks like this is it.

7 Q. Let's go to the way bottom.

8 "Surgery for stress incontinence has
9 potential side effects, such as a urinary tract
10 infection or temporary trouble urinating, but 'the odds
11 are in your favor that these complications won't
12 happen,' Dr. Fitzgerald of Loyola University says."

13 Do you agree with him?

14 A. Based on those two complications, I
15 think that's a true statement.

16 Q. Then it says, "Any risks are far
17 outweighed by the likelihood that you will be cured.
18 It's rare to be worse off than when you started."

19 Do you agree with that?

20 A. I think that's a patient specific
21 comment that I wouldn't necessarily agree to, no.

22 Q. Well, if you take the patient population
23 overall, is it rare for a patient to be worse off than
24 when they started?

1 A. It can happen, but it's not common.

2 Q. Then there's a urinary incontinence
3 section, and then after that there's a link to this
4 National Association for Continence that I attached in
5 here.

6 You see this?

7 A. I do.

8 Q. And do you know whether you've actually
9 looked at this?

10 A. It's been a long while, if I had. It's
11 been probably a good four or five years since I have.

12 Q. All right. If there was something in
13 this link that you strongly disagreed with, you would
14 have had at least some ability to go to the practice
15 manager and get this link taken off, correct?

16 A. Assuming I had looked at it, I would say
17 that's true.

18 Q. All right. Do you know whether you ever
19 looked at this?

20 A. Like I said, it's been a long while and,
21 quite frankly, this entire document is bringing back
22 memories, some of them fond, in fact.

23 Q. Okay. Let's just go to the bottom of
24 this link, the bottom of Page 1 of 6 of this link.

1 A. Okay.

2 Q. It says, "There are three main types or
3 approaches of midurethral slings: retropubic,
4 transobturator and the newer mini sling. All three are
5 effective, but because the standard retropubic and
6 transobturator slings enjoy 10 to 15 years of use and
7 an impressive number of reports of their effectiveness,
8 they are considered the gold standard for surgical
9 treatment of SUI in women by many leading clinicians."

10 First, did I read that correctly?

11 A. You did.

12 Q. And do you agree with it?

13 A. I do not.

14 Q. And what part of it don't you agree
15 with?

16 A. I would disagree that it's the gold
17 standard for surgical treatment of SUI, number one.
18 And, unfortunately, at the time that this particular
19 manifest was being produced, in large part to my
20 analysis, it was being produced in response to some of
21 the FDA warnings that had come out at that time
22 speaking towards complications.

23 Q. Who is the National Association for
24 Continence or what is?

1 A. I don't know.

2 Q. The bottom of your letterhead it says
3 recipient of the joint commission's gold seal of
4 approval?

5 A. Yes.

6 Q. What is that?

7 A. Joint commission is a governing body --

8 Q. I'm sorry. I don't mean to cut you off,
9 but Fred needs to catch a plane. I know what the joint
10 commission is.

11 What's the gold seal of approval?

12 A. I believe that's -- assignment of our
13 practice carrying itself in a fashion that's compliant
14 with the joint commission's highest standards.

15 Q. Okay. So the notion of tying the word
16 gold to a high level of performance is not unusual in
17 the medical profession, correct?

18 A. It's a word that's used in different
19 arenas in medicine, this is true.

20 Q. Do you believe that there is a gold
21 standard for the treatment of SUI?

22 A. I do not.

23 Q. Have you heard the phrase compliant when
24 referring to patients?

1 A. I have.

2 Q. This patient is compliant, this one is
3 not, et cetera; are you familiar with that?

4 A. Yes, yes.

5 Q. From your review of the medical records,
6 was Mrs. Pridmore a compliant patient?

7 A. Not especially.

8 Q. Was she a cooperative patient?

9 A. Not especially.

10 (Document marked for identification as
11 Walmsley Pridmore Deposition Exhibit No. 3.)

12 BY MR. MORIARITY:

13 Q. I would like you to look at that for
14 just a second. I took this list out of testimony you
15 gave in another case when you were asked a sequence of
16 questions about whether these were potential risks and
17 complications of any pelvic floor surgery, okay. In
18 some instances you said yes and in other instances you
19 said yes, to some degree, okay, to be fair. So I want
20 to go through this.

21 MR. THOMPSON: Let me object to the
22 document as a lawyer created summary that is
23 incomplete and doesn't have the appropriate
24 something. That's my objection. Go ahead.

1 BY MR. MORIARITY:

2 Q. It comes from Page 33 of one of your
3 depositions, and I can't remember if it's Ridgely or
4 Fox, okay. Let's just go through this.

5 Is infection a potential risk or
6 complication of any pelvic surgery repair for stress
7 urinary incontinence?

8 A. I'm happy to proceed, but am I to
9 understand that we are discussing strictly stress
10 urinary incontinence surgery based on your question?

11 Q. Okay. I'll ask it a different way.
12 Good point.

13 Is infection a potential risk and
14 complication with any pelvic floor surgery?

15 A. Yes.

16 Q. Is bleeding a potential complication of
17 any pelvic floor surgery?

18 A. Yes.

19 Q. Are wound complications a potential risk
20 of any pelvic floor surgery?

21 A. Yes.

22 Q. Is damage to an adjacent organ a
23 potential risk of any pelvic floor surgery?

24 A. Yes.

1 Q. Fistula formation?

2 A. Yes.

3 Q. Voiding dysfunction?

4 A. Yes.

5 Q. Scarring?

6 A. Yes.

7 Q. Adhesions?

8 A. Yes.

9 Q. Nerve damage?

10 A. Yes.

11 Q. Neuromuscular problems?

12 A. I agree.

13 Q. I'm going to go off chart for a second.

14 Is pelvic pain a potential risk or

15 complication of any pelvic floor surgery?

16 A. Yes.

17 Q. Is long-term pelvic pain a potential

18 risk and complication of any pelvic floor surgery?

19 A. Some more than others, but yes.

20 Q. And is dyspareunia a potential

21 complication of any pelvic floor surgery?

22 A. Yes.

23 Q. Is long-term dyspareunia a potential

24 complication of any pelvic floor surgery?

1 A. Once again, some more than others, but
2 yes.

3 Q. And the potential need for surgery in
4 the future to address complications or a failure of the
5 first surgery is a potential risk or complication, is
6 it not?

7 A. Some more than others, but yes.

8 (Document marked for identification as
9 Walmsley Pridmore Deposition Exhibit No. 4.)

10 BY MR. MORIARITY:

11 Q. Handing you Exhibit 4, I will represent
12 to you that is the patient brochure for the TVT family
13 of products that was in effect in 2007 when Dr. Diamond
14 put the TVT-O in Mrs. Pridmore. I've only got a couple
15 questions for you about this. This is not on your
16 reliance list, correct?

17 A. It is not.

18 Q. Do you know whether you have ever seen
19 this document before?

20 A. I have seen this before.

21 Q. In general, is it a discussion of the
22 problem of incontinence and some of the potential
23 solutions?

24 A. I think that's fair.

1 Q. Does it also include at least some of
2 the potential risks and complications of a TVT
3 procedure, whether you're using a retropubic approach
4 or an obturator approach? And if you need to, go back
5 to Page 14, there is a specific section about what are
6 the risks, 14 and 15.

7 A. May I hear that question one more time,
8 please.

9 Q. I mean, there is a general discussion of
10 some of the potential risks and complications, correct?

11 A. Yeah, on Pages 14 and 15 there is some
12 discussion about some of those risks.

13 Q. Do you know whether or not Dr. Diamond
14 kept pamphlets like this in his office available for
15 patients like Mrs. Pridmore?

16 A. I don't have an answer to that.

17 Q. Does that mean you don't know if he did
18 or did not?

19 A. Yes.

20 Q. Okay.

21 (Document marked for identification as
22 Walmsley Pridmore Deposition Exhibit No. 5.)

23 MR. MORIARITY: Handing what I've marked
24 as Exhibit 5.

1 Fred, do you need one of these, or have
2 you seen enough of these?

3 MR. THOMPSON: That actually was made an
4 exhibit on Friday, but go ahead. None of us
5 know enough about what was said on Friday for
6 me to raise any kind of real objection to it,
7 but this was put in front of him on Friday.

8 MR. MORIARTY: I have very few questions
9 about this.

10 BY MR. MORIARTY:

11 Q. You have seen this before, obviously?

12 A. I have.

13 Q. Had you seen it before Friday?

14 A. I have.

15 Q. Had you ever seen it in any part of your
16 own training when you were learning how to put in
17 synthetic midurethral slings?

18 A. I recall, once again, perusing this and
19 not closely examining it at the time that it was
20 produced, but I do recall seeing this some time ago, I
21 do.

22 Q. And, in general, it's a fairly lengthy
23 document, 15 or so pages with citations, and it's about
24 incontinence and treatments for incontinence, how to

1 put in TVTs and some of the risks of TVTs, correct?

2 A. I think that's a fair comment, yes.

3 Q. And do you know whether Dr. Diamond ever
4 saw this document?

5 A. I do not know that.

6 Q. And let me ask you one more short set of
7 questions, and then we'll go off the record for a
8 second, okay.

9 I assume you reviewed the instructions
10 for use for TVT-O that would be applicable in 2007 when
11 this implant was done, correct?

12 A. I did, yes.

13 Q. And I'm sure you have certain opinions
14 about that, you've probably been asked about those last
15 Friday, correct, to some extent?

16 A. Well, that was TVT Secur.

17 Q. Okay. The opinions you have regarding
18 the IFU, are they set forth in your report in this
19 case?

20 A. They are.

21 Q. Do you know whether Dr. Diamond relied
22 on the IFU when making decisions about operating on
23 Mrs. Pridmore?

24 A. I do not.

1 (Document marked for identification as
2 Walmsley Pridmore Deposition Exhibit No. 6.)

3 BY MR. MORIARITY:

4 Q. Just so the record is clear, Exhibit 6
5 would be the IFU applicable to TVT-O in 2007, correct?

6 A. Yes.

7 Q. You don't know whether he relied on this
8 at all, correct?

9 A. I do not.

10 Q. You don't know what sources of
11 information Dr. Diamond relied on or didn't rely on in
12 his entire thinking and approach to Mrs. Pridmore as a
13 patient, correct?

14 A. It would be mere conjecture.

15 Q. So by 2007 there was a substantial
16 amount of medical literature published about TVT
17 retropubic, some about TVT obturator, correct?

18 A. Yes.

19 Q. A lot about efficacy and a lot about
20 safety, correct?

21 A. Yes.

22 Q. And you don't know how much of that
23 literature he was aware of or relied on in making
24 decisions about Mrs. Pridmore, correct?

1 A. That's correct.

2 MR. MORIARTY: Let's take a break here.

3 (Pause in deposition at 2:24 p.m.)

4 (Deposition resumes at 4:56 p.m.)

5 BY MR. MORIARTY:

6 Q. So I asked you some questions about this
7 exhibit, this chart that I marked and which
8 Mr. Thompson objected to, it was Exhibit 3, okay?

9 A. Yes.

10 Q. Do you believe that you knew in 2007
11 that these were potential risks and complications of
12 pelvic floor surgery?

13 A. Not all of them, but most of them.

14 Q. Which ones do you think you didn't know
15 were potential risks and complications of pelvic floor
16 surgery in 2007?

17 A. Well, particularly the last three, not
18 necessarily the final one, but with regards to pelvic
19 pain and pelvic intercourse, the nature of them as far
20 as long term and severity.

21 Q. I think you meant to say painful
22 intercourse, not pelvic intercourse.

23 A. I meant to say painful intercourse. I
24 was alluding to pelvic pain and painful intercourse,

1 yes.

2 Q. And, of course, we don't know what
3 Dr. Diamond knew about these potential risks and
4 complications on this chart, correct?

5 A. That's correct.

6 Q. We don't know if he knew them all or
7 didn't know them all, right?

8 A. I would agree with that, yes.

9 Q. And do you typically tell patients about
10 all of these in your informed consent discussions?

11 A. I do.

12 Q. Have you done any analysis of the number
13 of urinary tract infections that Hope Pridmore had
14 prior to September of 2007 versus after September of
15 2007?

16 A. The analysis done is really related in
17 the clinical history that I've provided on my report,
18 as well as my review of the medical records that are
19 enclosed in my report.

20 Q. So in the last page of your report in
21 the last paragraph before Case Specific Opinion Number
22 2, you're talking about the UTIs, and you say, although
23 she had a history of UTIs pre sling, the frequency and
24 severity of her UTIs post sling were much different and

1 more severe, so my question is have you done some sort
2 of analysis of the number, let's just talk about
3 frequency right now, the number of UTIs in the years
4 before this mesh implant and the years after?

5 A. More in the years after than before.

6 Q. Okay. But you can't compare the
7 frequency of them before and after unless you do an
8 analysis mathematically of both periods, correct?

9 A. I agree with that.

10 Q. And did you have all of the medical
11 records available to you from the years prior to
12 implant to assess the severity of them?

13 A. I don't know if I had every single
14 medical record concerning Mrs. Pridmore prior to 2007,
15 so it's hard to answer that question.

16 Q. Okay.

17 (Document marked for identification as
18 Walmsley Pridmore Deposition Exhibit No. 7.)

19 BY MR. MORIARITY:

20 Q. Exhibit 7, these are the records of
21 Dr. Diamond. Did you have these available to you for
22 review?

23 A. I did, I did, yes, sir.

24 Q. I'd like you to go to Bates Page 3.

1 A. Yes.

2 Q. You see at the bottom it's signed
3 November 9, 2005?

4 A. Yes.

5 Q. Am I correct that Dr. Diamond saw
6 Mrs. Pridmore in many years long before this, and then
7 there was a hiatus, and this is when she returns?

8 A. That's correct.

9 Q. All right. So if you go to Page 4, the
10 complaint she was making that day was losing urine
11 since very hard fall, correct?

12 A. Yes.

13 Q. Does that make any anatomic physiologic
14 sense to you? Is there some way that you can injure
15 yourself in a fall that would increase your
16 incontinence of any type?

17 A. I have seen this once before in the
18 setting of a motor vehicle accident, where someone
19 started suffering stress incontinence following that
20 motor vehicle accident.

21 Q. So it's at least you used the word
22 earlier, feasible, wasn't it?

23 A. Plausible.

24 Q. Plausible, so it's plausible?

1 A. Yes.

2 Q. Okay. And then down in the history
3 section for the patient, diabetes, high blood pressure
4 and nervous disorder are all checked, correct?

5 A. Correct.

6 Q. Near your left hand?

7 A. Yes, sir.

8 Q. Next page, her last menstrual period was
9 1981, correct?

10 A. Yes.

11 Q. So she's menopausal by this period of
12 time; is that right?

13 A. That's correct.

14 Q. Does that increase the risk of vaginal
15 atrophy?

16 A. Yes, it can.

17 Q. Does it increase the risk of
18 dyspareunia?

19 A. In the presence of vaginal atrophy, yes.

20 Q. And of course she's G5, P5, so she has
21 an increased risk for not only incontinence but pelvic
22 organ prolapse, correct?

23 A. That's correct.

24 Q. In the last section under urinary tract

1 history, what does it say next to urinary tract
2 infection?

3 A. Always since childhood.

4 Q. So at least there's some evidence in
5 these records that prior to November of 2009, she's had
6 chronic UTIs, correct?

7 A. I call them recurrent, but I think the
8 two terms are exchangeable.

9 Q. All right. Now, later we'll get to
10 this. There's a couple diagnoses in the chart. I want
11 to make sure I understand what you think these are.

12 So there's cystitis. First of all, how
13 would you define cystitis?

14 A. Cystitis, as broken down from the Latin
15 derivation, is inflammation inside of the bladder.

16 Q. Okay. And then there's -- can a patient
17 have chronic cystitis?

18 A. Yes, there can be that diagnosis
19 rendered.

20 Q. What is chronic follicular cystitis?

21 A. This is one of those instances where I'm
22 not clear as to the semantics of follicular, so I'm
23 really unable to answer that question, primarily
24 because it's not typically a term I see or use in my

1 clinical practice.

2 Q. Was that in the pathology report from
3 Dr. Wilks in 2015? Is that where that term came from
4 in this case?

5 A. Yes, yeah, with the biopsy that was
6 done, and I think perhaps it was a pathological
7 terminology utilized.

8 Q. So let me make sure I understand. If a
9 patient has enough urinary tract infections, whether
10 you call them chronic or recurrent, can they develop
11 actual changes to the interior lining of the bladder
12 where they develop cysts or nodes or follicles,
13 something like that?

14 A. In my experience, one can perform
15 bladder biopsies on patients who've had recurrent
16 and/or chronic infections and especially if they have
17 an active infection or inflammatory event, you can
18 actually demonstrate pathological findings that are
19 consistent with inflammation.

20 Q. All right. And at least according to
21 the pathology report that we have in this case from
22 2015, is that what the finding was?

23 A. That's correct.

24 Q. So back to Bates Page 5 of Dr. Diamond's

1 records.

2 A. Yes.

3 Q. At the time of this she had pain with
4 urination, difficulty with stream and was not
5 completely emptying her bladder, correct?

6 A. Yes, that's what she complained about.

7 Q. She also checked urgency and with
8 coughing, laughing, sneezing and exercise, correct?

9 A. Yes.

10 Q. And then all the time, whatever that
11 means, right, the bottom?

12 A. She did check that off.

13 Q. Have you ever seen a form like this? Is
14 this some sort of standard form that urologists use?

15 A. I mean, I've seen forme frustes of this
16 but not this specific form, yes.

17 Q. So if you go up to Page 8, this is an
18 office note from November 9, 2005?

19 A. Yes.

20 Q. And in the second full paragraph it
21 says, "when she has infection she has discomfort in the
22 bladder."

23 Do you see that?

24 A. I do.

1 Q. Is that a common finding -- I'm sorry.

2 Let me rephrase that.

3 Is bladder discomfort a common finding
4 in women who have urinary tract infections?

5 A. It can be.

6 Q. And then in the last big paragraph it
7 says sounds like she had a Marshall-Marchetti procedure
8 done many years ago, right?

9 A. Correct.

10 Q. So if she's now having incontinence,
11 that MMK procedure did not provide permanent relief for
12 her stress incontinence, correct?

13 A. That would be my conclusion.

14 Q. Page 12, please. This is -- did I miss
15 something?

16 A. No, I remember reading these notes, and
17 I love when comments such as coming in to see me feisty
18 as always but in good cheer, I just find that somewhat
19 amusing. Pardon me.

20 Q. That's fine.

21 But this describes increasing problems
22 of leakage, getting up four times a night to urinate
23 and leaking during the night too, correct?

24 A. Correct.

1 Q. That's what he is noting here?

2 A. Correct.

3 Q. So she is not only getting up to go to
4 the bathroom, nocturia, but she's actually having some
5 leakage while she's asleep?

6 A. Yes.

7 Q. And she had an infection even as of that
8 date, correct?

9 A. Correct.

10 Q. Let's go out to Page 22.

11 Are you there?

12 A. I'm here, yes.

13 Q. So this is his operative note from
14 September 4th, 2007, correct?

15 A. Yes.

16 Q. And his diagnosis was mixed urinary
17 incontinence. Would you agree with that?

18 A. That's correct.

19 Q. And he put in a TVT-O, correct?

20 A. Yes, sir.

21 Q. And that was a reasonable thing to do
22 and was within the standard of care at that point,
23 correct?

24 A. I agree.

1 Q. Do you know for a fact, from looking at
2 any other records, whether this was mechanically cut or
3 laser cut TVT-O?

4 A. My belief was at the time the laser cut
5 option wasn't available, but reading this operative
6 note, one can't draw that conclusion.

7 Q. Do you have any opinions in this case to
8 a reasonable degree of medical probability that she,
9 Mrs. Pridmore suffered some harm as a result of the way
10 this TVT-O was cut in the factory? I can tell you
11 there's nothing about it in your report. I'm just
12 wondering if you have such an opinion.

13 A. I'm just verifying your comment, and I
14 would agree with you, there's nothing in my report that
15 would speak to that, so I would not offer that opinion.

16 Q. All right. So if you look at Page 25,
17 which was the history and physical that he did before
18 the surgery?

19 A. Yes.

20 Q. In the second paragraph he refers to
21 significant degree of cystocele.

22 Do you see that?

23 A. I do see that.

24 Q. And we don't know why he didn't treat

1 it, but do you have any -- do you think that his
2 failure to treat the cystocele was below the standard
3 of care?

4 A. I don't.

5 Q. Does the failure to treat the cystocele,
6 for whatever reason, put her at increased risk for any
7 type of postoperative urinary tract difficulties?

8 A. Possibly.

9 Q. Which difficulties does it possibly
10 increase the risk of?

11 A. Well, one thing that I see and my
12 colleagues see in clinical practice with a significant
13 cystocele is a kinking effect at the bladder neck,
14 whereby the dropping of a cystocele can make it
15 difficult to evacuate the bladder completely.

16 Q. Okay. Go on.

17 A. Incomplete bladder emptying in and of
18 itself can be a risk factor for infection simply
19 relating to the stasis of the urine in the bladder.

20 Q. Did she ever have proven incomplete
21 bladder emptying?

22 A. I have not seen that in her medical
23 records.

24 Q. Any other risks that may put her -- any

1 other increased risk as a result of not repairing the
2 cystocele?

3 A. Perhaps the only real risk or other real
4 risk would be the progression of the cystocele towards
5 needing a repair.

6 Q. Okay. So and then in the next line it
7 says that she's got chronic cystitis.

8 Do you see that?

9 A. I do see that, yes.

10 Q. Do you have any reason to disagree with
11 Dr. Diamond's diagnosis at that point?

12 A. I only do insofar as you had mentioned
13 compliance of the patient, and given the fact that
14 she's been no noncompliant, I think it's difficult to
15 assign that diagnosis in the setting of a patient
16 that's not being regularly seen.

17 Q. And I think what you're implying is not
18 regularly being seen, hence not being regularly treated
19 for UTIs?

20 A. That would be part of my opinion, yes,
21 yes.

22 Q. All right. Did you see anything in any
23 of Dr. Diamond's records where Mrs. Pridmore complained
24 of pelvic pain or dyspareunia postoperatively?

1 A. Postoperatively.

2 Q. And I'm just talking about Diamond's
3 records.

4 A. No, I did not.

5 (Document marked for identification as
6 Walmsley Pridmore Deposition Exhibit No. 8.)

7 BY MR. MORIARITY:

8 Q. Exhibit 8, Doctor. Do you recognize
9 this as an emergency room -- I'm sorry -- do you
10 recognize this as a hospital admission history and
11 physical from Mrs. Pridmore's PCP, Dr. Alexander,
12 August 1, 2007?

13 A. Yes, sir.

14 Q. And the reason she was admitted was
15 persistent abdominal pain?

16 A. Yes.

17 Q. Under the past medical history section,
18 does it indicate that she had diabetes, hypertension,
19 chronic low back pain, chronic anxiety with depression
20 and hyperlipidemia?

21 A. Yes, sir.

22 Q. Are you going to make any claim -- I'm
23 sorry -- are you going to render any opinions in this
24 case that Mrs. Pridmore suffered any sort of

1 psychiatric harm as a result of her TVT-O?

2 A. I hadn't planned on it, no.

3 Q. All right. The fact that she's got
4 diabetes to whatever degree hers is controlled, is she
5 at increased risk for SUI and SUI recurrence
6 postoperatively?

7 A. Relating strictly to her diabetes?

8 Q. Yes, sir.

9 A. Not in the setting of well-controlled
10 diabetes I wouldn't opine that.

11 Q. Is hers well-controlled?

12 A. I'm not sure.

13 Q. Bottom line is if it's well-controlled,
14 it shouldn't be a risk factor; if it's poorly
15 controlled, it could be?

16 A. If it's poorly controlled it could be
17 more from the standpoint of a neurogenic type of a
18 voiding dysfunction.

19 Q. Some other kind of incontinence?

20 A. Correct.

21 Q. All right. Other than stress?

22 A. That's correct.

23 Q. I did not make extra copies of these. I
24 can mark them if we need to. These are notes from

1 Dr. Alexander's office, January 6, 2007.

2 Have you seen these notes before?

3 A. I believe I have, yes.

4 Q. This one which is just a month or so
5 after Mrs. Pridmore's surgery says, among other things,
6 that she complains of itching and burning in the
7 vaginal area, and she's got discharge.

8 Do you see that?

9 A. Is that a without discharge or with
10 discharge? I'm just not sure of that nomenclature
11 there.

12 Q. I'll reask the question.

13 A. Okay.

14 Q. Does it at least says she's complaining
15 of itching and burning in the vaginal area?

16 A. Yes.

17 Q. Could that be consistent with a urinary
18 tract infection?

19 A. Based on her presenting symptoms, I
20 would opine otherwise.

21 Q. In your opinion, what is she suffering
22 at this point? What is her problem at this point?

23 A. Well, in a lot of instances, the top
24 thing on my differential would probably be a candidal

1 vulvovaginitis, given the itching.

2 Moreover, with Mrs. Pridmore's history,
3 typically, the pain that she has with urinary tract
4 infections is more bladder or what I would call
5 suprapubic.

6 Q. So if I understand what you're saying,
7 this is more consistent with a vaginal infection, not a
8 urinary tract infection?

9 A. I would place vaginal infection above
10 urinary tract infection, yes.

11 Q. Okay. And then there's another note,
12 January 12, 2008. Have you seen this record in your
13 review of the materials?

14 A. I recall seeing this, yes.

15 Q. And on January 12th, 2008 her complaint
16 is patient complaints of swelling, soreness, vaginal
17 area, and I think it's no burning sensation?

18 A. Yeah, without a burning sensation, yes.

19 Q. And then something patient states that
20 daughter has I think it's MRSA and is concerned.

21 Do you see that?

22 A. I do see that, yes.

23 Q. That would be methicillin-resistant
24 staph aureus, if that says MRSA, that's what it would

1 be, right?

2 A. Correct, yes.

3 Q. Do you have an opinion to a probability
4 as to what her presenting complaint really is on this
5 day? Is it some form of infection or is it something
6 else?

7 A. I think infection would be in the
8 differential. If I had someone ask me to render
9 diagnoses, I would probably state vaginal pain and
10 vaginal swelling or edema, if I had to attribute a
11 diagnosis to the complaint.

12 Q. Now, I know it says soreness. It
13 doesn't say vaginal pain in this note, does it?

14 A. It does not say vaginal pain in this
15 note.

16 Q. Is there a note anywhere in the material
17 that you reviewed that actually says that Mrs. Pridmore
18 had vaginal pain?

19 A. I'd have to relook at the November 17th,
20 2011 note performed by Dr. Alsheik to definitively
21 answer that question.

22 Q. Give me that date again, please.

23 A. November 17th, 2011 Dr. Hassan Alsheik,
24 because he did memorialize that since her sling surgery

1 she had been having worsening pain, and I just don't
2 recall if the term vaginal pain was used.

3 MR. MORIARITY: I'm not sure what's
4 going on here. I believe for some reason --
5 yeah, the November 17 note, for some reason, is
6 split into two pieces. So I'm going to mark
7 these 9 and 10, but I think this is the note.

8 (Documents marked for identification as
9 Walmsley Pridmore Deposition Exhibit Nos. 9
10 and 10.)

11 (Witness reviews document.)

12 BY MR. MORIARITY:

13 Q. Did you find something you want to tell
14 me about?

15 A. Yes, sir.

16 Q. In which exhibit?

17 A. On Bates 413 of Exhibit 10.

18 Q. Okay. Where?

19 A. What it states is "the patient has a
20 past medical history of a sling placement about 8 years
21 ago done by Dr. Diamond. However since then she has
22 been having worsening pain, as well as frequency,
23 urgency, recurrent urinary tract infections."

24 Q. But it doesn't give a location for the

1 pain in this note, correct?

2 A. Vaginal pain is not specifically stated
3 here.

4 Q. While we've got these notes out, let me
5 ask you about Number 9 first.

6 A. Yes, sir.

7 Q. Now, this is an electronic medical
8 record, correct?

9 A. Sure is.

10 Q. And in the first page there is a review
11 of systems, genitourinary section, correct?

12 A. Yes.

13 Q. So positive for urgency, right?

14 A. Yes.

15 Q. And that's a problem she had before the
16 TVT-O, correct?

17 A. That's correct.

18 Q. Negative for dysuria, frequency and
19 difficulty urinating, correct?

20 A. That's what it states.

21 Q. And on the last page of 9, which is
22 Bates Page 397, is there a final diagnosis section way
23 at the bottom?

24 A. Yes.

1 Q. And the top one is cystitis, correct?

2 A. Yes, sir.

3 Q. And then in 10, on the first page, 411,
4 in the last paragraph it says, "Subsequently, she may
5 have to have ureterolysis or a sling release and this
6 will be done only if the patient has retention."

7 Do you see that?

8 A. I do.

9 Q. Was it ever shown that she had
10 retention?

11 A. To my knowledge, no, it was not.

12 Q. And, of course, she never had her sling
13 released, correct?

14 A. She did not.

15 Q. No doctor ever deemed that it was
16 necessary that she go to the OR for that kind of
17 procedure?

18 A. I'm not in complete agreement with that,
19 but she never did have it removed, that I would agree
20 with you on.

21 Q. And she had a cystoscopy which showed a
22 possible tumor in her bladder at that point, correct?

23 A. Yes, sir.

24 (Documents marked for identification as

1 Walmsley Pridmore Deposition Exhibit Nos. 11
2 and 12.)

3 BY MR. MORIARITY:

4 Q. Show you Exhibit 11 and 12. Are you
5 with me?

6 A. Yes.

7 Q. It's a lot of paper to keep straight.

8 A. Yes, indeed.

9 Q. Is 11 a note from April 2007?

10 A. Yes, sir.

11 Q. Prior to her TVT-O?

12 A. Yes, it is.

13 Q. And at this point she had urinalysis
14 positive for pyuria and leukocyte esterase, correct,
15 first page bottom of the history of present illness?

16 A. Yes.

17 Q. And then in the social history, does it
18 say she has not been sexually active for a long time?

19 A. This is what's stated.

20 Q. All right. And then if you go to Page
21 12, is this a note from December of 2013?

22 A. Exhibit 12 shows that, yes.

23 Q. And if you go kind of right in the
24 middle of the page here, there's a box for sexually

1 active, and the answer is no, correct?

2 A. Yes, sir.

3 Q. Did you find anywhere in any of the
4 medical records, including the most recent ones of
5 Dr. Wilks in 2015, any complaint of dyspareunia?

6 A. I did not.

7 (Document marked for identification as
8 Walmsley Pridmore Deposition Exhibit No. 13.)

9 MR. MORIARITY: Here's Exhibit 13. I
10 don't know if you remember this, Fred, but my
11 goal at every deposition is to leave with
12 substantially less paper than I arrived with.

13 BY MR. MORIARITY:

14 Q. This is Dr. Wilks' record from July 15,
15 2015.

16 Did you have these available in your
17 review of the materials?

18 A. I don't specifically recall seeing this
19 record.

20 Q. All right. It says here, "This patient
21 is a new patient being seen today for the first time
22 due to problems of bladder pain and recurrent urinary
23 tract infections."

24 Do you see that?

1 A. Yes.

2 Q. And then it describes she also has
3 urgency with urgency incontinence, stress incontinence,
4 intermittency, splitting and spraying of the stream,
5 dysuria and hesitancy.

6 Do you see that?

7 A. I do.

8 Q. She states that she has had the problem
9 for at least 45 years.

10 Do you see that?

11 A. I do.

12 Q. Are you going to attribute any of these
13 in your opinion to the TVT-O? Let's start with
14 urgency.

15 A. In part, yes.

16 Q. Why?

17 A. Because despite the fact that she had
18 that symptom prior to her surgery, she continued to
19 have it beyond the surgery as well.

20 Q. And isn't that a risk of the procedure?

21 A. It is.

22 Q. Isn't it a risk of any surgery for
23 stress urinary incontinence?

24 A. Yes, to some degree it is, this is true.

1 Q. Urge incontinence, are you going to
2 claim that that is a result of TVT-O?

3 A. I am.

4 Q. For the same reason we just discussed?

5 A. To my review of the medical records, it
6 appears that her urgency incontinence is worse.

7 Q. And how are you quantifying that? What
8 is the basis for your saying it's worse?

9 A. Well, when she first presented to
10 Dr. Diamond with this complaint, there was never any --
11 she had been treated with Vesicare in the past for her
12 urgency urinary incontinence; however, those
13 medications were no longer effective after her sling.

14 Q. Well, in a patient of this BMI and
15 weight, G5, P5, diabetic, smoking history, isn't urge
16 incontinence simply a risk of any stress urinary
17 incontinence surgical procedure?

18 A. It is, yes.

19 Q. So stress incontinence if she has it is
20 a recurrence, correct?

21 A. That's correct.

22 Q. And that's a risk of any SUI procedure,
23 correct?

24 A. I would agree with that, yes.

1 Q. Intermittency, do you believe that's in
2 your opinion to a probability the result of TVT-O?

3 A. I do.

4 Q. Why?

5 A. I do agree with that.

6 Q. Why?

7 A. Well, once again, the procedure she had
8 because of the nature of the fibrosis and scarring
9 inherent to placing this procedure can create an
10 obstructive voiding pattern that would be equivalent to
11 intermittency, splitting and spraying of her stream.

12 Q. Can you get that with autologous fascial
13 slings?

14 A. You can.

15 Q. Is there any Level 1 evidence to
16 indicate that that kind of a complaint has a higher
17 incidence with synthetic midurethral slings than it
18 does with autologous fascial slings?

19 A. I think from a quantitative standpoint,
20 no.

21 Q. Splitting and spraying, are you going to
22 render an opinion that that is from TVT-O?

23 A. I would with the same thought process
24 relating to the intermittency discussion you and I just

1 had.

2 Q. And is it also a risk with autologous
3 fascial slings?

4 A. Yes, it is.

5 Q. Dysuria, are you going to claim -- or
6 I'm sorry -- are you going to render an opinion that
7 that is a result of TVT-O?

8 A. I would not.

9 Q. What about hesitancy?

10 A. Once again, it's one of those
11 obstructive voiding symptoms that I pair with
12 intermittency and splitting/spraying.

13 Q. So it's a risk of any SUI procedure?

14 A. Quantitatively, yes.

15 Q. All right. On the second page of this
16 note, which is Bates Page 9.

17 A. Yes.

18 Q. Do you see the medication section?

19 A. I do.

20 Q. Do any of those medications have urinary
21 tract side effects?

22 A. Yes.

23 Q. All right. So if I was to go get the
24 Physician's Desk Reference for any of those, do most of

1 them have urinary tract side effects?

2 A. Several of them do, yes.

3 Q. And which ones off the top of your head
4 do you know have some urinary tract side effects?

5 A. Neurontin, Oxybutynin, Wellbutrin,
6 Vicodin, Xanax, Paxil.

7 Q. So that was Neurontin, Oxybutynin,
8 Vicodin, Xanax and Paxil, correct?

9 A. That's correct.

10 Q. Did I miss one?

11 A. Did you say Wellbutrin?

12 Q. No, I did not.

13 A. Wellbutrin as well.

14 Q. She is apparently not on a diuretic. Is
15 she on a diuretic for her hypertension?

16 A. No, sir.

17 Q. And then Dr. Wilks mentions here at the
18 bottom of the social history is not sexually active,
19 correct?

20 A. Yes.

21 Q. On the next page, Page 10, at the top
22 there's a physical exam of the genitalia, correct?

23 A. Yes.

24 Q. She was tender to the bladder with

1 palpation, correct?

2 A. Yes.

3 Q. That is not where TVT is, correct?

4 A. It should not be there.

5 (Document marked for identification as
6 Walmsley Pridmore Deposition Exhibit No. 14.)

7 BY MR. MORIARITY:

8 Q. Handing you Exhibit 14, is this another
9 note from Dr. Wilks, October 1, 2015?

10 A. Yes, sir.

11 Q. All right. And the chief complaint is
12 recurrent UTIs?

13 A. Correct.

14 Q. Which is noted here she has had
15 virtually a lifetime of recurrent urinary tract
16 infections?

17 A. Correct.

18 Q. And the bladder pain is consistent with
19 urinary tract infections; is it not?

20 A. I would agree.

21 Q. And, again, on the second page, which is
22 Bates Page 6 here, under the physical exam, genitalia,
23 she was tender over the bladder, not the urethra,
24 correct?

1 A. That's correct.

2 Q. And there's been no finding through any
3 of these records that she has what you would call an
4 extrusion or an exposure of her mesh into the vagina,
5 correct?

6 A. I agree with that.

7 Q. She never had an erosion of mesh into
8 the urethra or the bladder either; is that right?

9 A. No, sir, not to my knowledge.

10 Q. And then he does, at Pages 9 and 10, a
11 procedure, he does a cystoscopy, correct?

12 A. Yes, sir.

13 Q. And that's where he takes this biopsy
14 that goes to the pathology department, right?

15 A. Right.

16 Q. And just explain in a sentence or two
17 what the fulguration procedure is designed to do?

18 A. When one either identifies bleeding or
19 performs a biopsy of a lesion, the fulguration process
20 essentially cauterizes and obliterates the bleeding
21 from that lesion or from the bleeding point.

22 Q. Okay. Did you do any independent
23 research on moderate, chronic follicular cystitis for
24 purposes of this case?

1 A. I did not.

2 Q. Is it a diagnosis that you've ever made
3 in a patient?

4 A. It's a pathologic diagnosis, so not
5 being a pathologist, I'm not -- I mean, if I'm
6 understanding the biopsy results demonstrating such, I
7 have not seen a pathology report in my patients
8 documenting that.

9 Q. Have you ever diagnosed cystitis in a
10 patient?

11 A. I have.

12 Q. What about chronic cystitis?

13 A. I have.

14 Q. Did you see in any of Dr. Wilks' notes
15 in 2015 or 2016 if you saw her in that year any
16 complaints of either vaginal pain, chronic pelvic pain
17 or dyspareunia?

18 A. I have not seen those.

19 Q. Did Dr. Wilks ever attribute
20 Mrs. Pridmore's urinary tract infections to her TVT-O?

21 A. Not directly, no.

22 Q. Did he do it indirectly?

23 A. I don't believe he attributed her pain
24 to anything specifically, directly or otherwise.

1 Q. Okay. Can cystitis be painful?

2 A. It can.

3 Q. Have you ever seen any peer reviewed
4 medical literature to indicate that TVT can cause
5 chronic follicular cystitis?

6 A. I have never seen that.

7 Q. Is it your opinion that the TVT-O in
8 this case has caused Mrs. Pridmore to have more and/or
9 more severe urinary tract infections than she did
10 preop, premesh implant?

11 A. That being a two part question, I would
12 say no to quantitative, but yes to qualitative.

13 Q. What evidence is there in these medical
14 records or Mrs. Pridmore's deposition to indicate that
15 she has more severe urinary tract infections following
16 her TVT-O than she did before?

17 A. Well, there are two reasons. One is
18 that there's certainly a plethora of data suggesting
19 she has infection after infection after infection
20 following the procedure, and I full well admit I don't
21 have records prior to her sling procedure, all I have
22 is a history of chronic/recurrent UTIs.

23 And the second basis for my opinion is
24 the fact that in no instance was she ever hospitalized

1 for an infection prior to her sling insertion, whereas
2 afterwards she was.

3 Q. Are you done with your answer?

4 A. Yes, sir.

5 Q. As she ages is she going to be at
6 increased risk for urinary tract infections, both more
7 of them and potentially more severe?

8 A. Well, I guess it depends on what
9 concomitant factors are occurring with the aging
10 process.

11 Q. Well, let's just put Mrs. Pridmore, her
12 age, her menopausal status, so she's going to be even
13 further out from estrogen, natural estrogen, her
14 obesity with, as we discussed before, the increased
15 risk that she can't wipe properly, therefore, she may
16 have more bacteria in that region to begin with, isn't
17 she at increased risk, just by those factors, for more
18 and more severe UTIs?

19 A. I would say for some of them, yes.

20 Q. For some of the UTIs or some of the
21 factors that I mentioned?

22 A. Some of the factors you mentioned.

23 Q. Which factors?

24 A. Well, obesity, presuming that her

1 obesity is evolving. I wouldn't necessarily agree with
2 vulvovaginal atrophy insofar as -- despite the fact
3 that there may be some diminished estrogen, I have not
4 seen any medical records or data to the fact of her
5 having this condition or it being treated actively or
6 otherwise.

7 Q. Does her noncompliance with treatment
8 either with antibiotics, weight loss, some of these
9 other factors increase her risk that she is going to
10 have more and more severe UTIs?

11 A. Once again, with some of those factors,
12 I would agree, yes.

13 (Document marked for identification as
14 Walmsley Pridmore Deposition Exhibit No. 15.)

15 BY MR. MORIARITY:

16 Q. Handing you what I've had marked as
17 Exhibit 15, was this note, I believe from Dr. Slotar or
18 his office in the materials available for you to
19 review?

20 A. I recall seeing this, yes.

21 Q. I think this is actually electronically
22 signed by James Cantorna, M.D., correct?

23 A. Yes, sir.

24 Q. She is there to get established,

1 correct, that's the reason in Exhibit 15 that she's
2 there, right? So she's there to get established,
3 right?

4 A. Yes, sir.

5 Q. And under review of systems, under
6 genitourinary it specifically says no pelvic pain and
7 no incontinence, correct?

8 A. It does state that.

9 Q. All right.

10 (Document marked for identification as
11 Walmsley Pridmore Deposition Exhibit No. 16.)

12 BY MR. MORIARITY:

13 Q. Then he sees her or somebody in that
14 office sees her September 27, 2012, correct?

15 A. Yes.

16 Q. And she is there because she's got
17 complicated urinary tract infection, right?

18 A. True.

19 Q. It says here, "controlled, poorly
20 compliant hypertensive diabetic with morbid obesity, 57
21 years old."

22 Do you agree with that?

23 A. I agree with what it says, yes.

24 Q. "Genitourinary: No dysuria, no pelvic

1 pain, no vaginal discharge, no incontinence, no
2 dysmenorrhea and no unexplained vaginal bleeding."

3 Is that what it says at least in this
4 medical record?

5 A. That's what it says at least in that
6 medical record, yes.

7 Q. And in the current medication list,
8 there are 14 items; are there not?

9 A. Yes, sir.

10 Q. Some of these have urinary tract side
11 effects?

12 A. Yes.

13 (Document marked for identification as
14 Walmsley Pridmore Deposition Exhibit No. 17.)

15 BY MR. MORIARITY:

16 Q. Handing you what's been marked as
17 Exhibit 17, was this note available for your review in
18 the materials?

19 A. Yes, sir.

20 Q. This is an operative note; is it not?

21 A. Yes, it is.

22 Q. Left total knee replacement in November
23 of 2013?

24 A. Correct.

1 Q. And this is the implantation of a
2 foreign body into her knee, correct?

3 A. Yes.

4 Q. And likely went with considerable
5 informed consent about the potential risks and
6 complications of whatever knee replacement device was
7 used, correct?

8 A. I mean, I can't comment on that, having
9 not seen the consent for this procedure.

10 Q. Would you expect that that would take
11 place?

12 A. I would.

13 Q. Okay. Tell me your opinion about what
14 complications of TVT-O Mrs. Pridmore suffered that are
15 not in some way referred to in the IFU?

16 A. Vaginal pain and voiding dysfunction.

17 Q. Are you done with your answer?

18 A. Yes, sir.

19 Q. I think I marked an IFU somewhere.
20 Isn't there something about urinary tract dysfunction
21 in the IFU?

22 A. I can read what I have.

23 Q. Go ahead. You're reading from your
24 report, correct?

1 A. Yes, sir, but I took that basically
2 verbatim out of the IFU, and what it states is "over
3 correction, i.e. too much tension applied to the tape,
4 may cause temporary or permanent lower urinary tract
5 obstruction."

6 Q. If you go up in the Warnings and
7 Precautions section, it says, "As with other
8 incontinence procedures, de novo detrusor instability
9 may occur following a suburethral sling procedure
10 utilizing the Gynecare TVT Obturator System. To
11 minimize this risk, make sure to place the tape as
12 described above."

13 Do you see that?

14 A. I don't. I don't have a copy of the IFU
15 in front of me.

16 Q. Do you trust me that I just read that
17 correctly from the IFU?

18 A. I do.

19 Q. All right.

20 A. Yes.

21 Q. Do you believe that Mrs. Pridmore had de
22 novo detrusor instability after her TVT-O?

23 A. I do not.

24 Q. Now, earlier when I asked you about this

1 list, you said that you were aware probably by 2007
2 that voiding dysfunction was a potential risk of this
3 procedure, correct?

4 A. That's correct.

5 Q. Do you believe that voiding dysfunction
6 was generally an item that was discussed in the
7 published medical literature regarding midurethral
8 slings by 2007?

9 A. Quantitatively I do, yes.

10 Q. So what you're referring to is this more
11 severe that you believe she suffered, correct?

12 A. I would opine more severe, and, also, I
13 would add to that the fact that Dr. Diamond met the
14 standard of care in terms of his implanting technique
15 and that the IFU, when it speaks to either de novo
16 urgency, incontinence, as you quoted to me, or to lower
17 urinary tract obstruction that might be temporary or
18 permanent, as I quoted to you, it was provided in the
19 context of the sling not being placed properly, over
20 tensioned or not following the instructions in the IFU.

21 Q. If you were going to publish a case
22 report about Mrs. Pridmore and truly use the scientific
23 method, wouldn't you have to have substantially more
24 information about the years of urinary tract infections

1 prior to September of 2007 in order to compare not only
2 the incidence but the severity of them?

3 MR. THOMPSON: Object to the form.

4 THE WITNESS: I think that would be very
5 helpful.

6 BY MR. MORIARITY:

7 Q. But if you were going to -- if you
8 really wanted to do a good scientific comparison, you
9 would have to have that data, correct?

10 MR. THOMPSON: Object to the form.

11 THE WITNESS: It would be very helpful
12 to know the severity and nature of her urinary
13 tract infections prior, I agree with that.

14 BY MR. MORIARITY:

15 Q. But your opinion in this case that her
16 urinary tract infections were more severe, for example,
17 is your opinion based on, frankly, some incomplete
18 data, correct?

19 MR. THOMPSON: Object to the form.

20 THE WITNESS: Well, I reviewed as much
21 data as I was given and the data that was
22 provided to me doesn't provide as much in the
23 way of medical records prior to her sling
24 implantation. Why that is, I can't answer.

1 BY MR. MORIARITY:

2 Q. I'm not trying to imply that you
3 personally did a shoddy job in your analysis.

4 Because of the number of years involved
5 and the number of medical records that simply aren't
6 available, like the old Dr. Diamond records, for
7 example, we just don't have that data, it's just part
8 of the analysis, correct?

9 A. Correct.

10 Q. But in order to do the best scientific
11 analysis of this question, you would need more data,
12 correct?

13 A. It would be very helpful, I would agree
14 with that.

15 Q. You didn't do a general TVT-O report,
16 did you?

17 A. I didn't provide one today, no, sir.

18 Q. Did you ever write one, a TVT-O report?

19 A. Other than the reports that I've
20 generated today, I have not.

21 Q. What is this -- to the best of your
22 knowledge, from the published medical literature, what
23 is the incidence of severe -- I'm sorry -- what is the
24 incidence of a synthetic midurethral sling causing

1 severe chronic urinary tract infections?

2 A. Well, that's a hard question to answer
3 because I don't know if there's been a specific table
4 that would provide said data, so I probably have to
5 give you a conjecture as to what that answer would be.

6 Q. Okay. Conjecture being speculation?

7 A. It would be probably speculative.

8 Q. What is your speculation?

9 A. I would say in the single digit
10 percentages, probably 5% or less.

11 Q. 5% or less. In your personal experience
12 with synthetic midurethral slings, is the incidence of
13 severe urinary tract infections very low?

14 A. It is.

15 Q. Can other types of stress urinary
16 incontinence procedures, such as a Burch or an
17 autologous fascial sling, potentially cause severe
18 urinary tract infections?

19 A. Potentially, yes.

20 MR. MORIARITY: Let's go off the record
21 for a second.

22 (Pause.)

23 BY MR. MORIARITY:

24 Q. Do you get the journal Urology?

1 A. I do.

2 Q. Do you read it?

3 A. I do.

4 Q. Is it generally reliable?

5 A. I utilize it to help me increase my fund
6 of knowledge as a urologist.

7 Q. Dr. Mock wrote an article comparing
8 autologous fascial slings with synthetic midurethrales
9 in Urology, and Dr. Kahn offered a similar kind of
10 comparison in the British Journal of Urology in 2015?

11 A. Yes.

12 Q. Have you read either of those?

13 A. I have seen those, yes.

14 Q. And they're not in your reliance list,
15 correct?

16 A. Not in this set of documents, no.

17 Q. Did either of those articles conclude
18 that autologous fascial slings were statistically
19 significantly safer and more effective than synthetic
20 midurethral slings?

21 A. Well, certainly I can answer from the
22 standpoint of effectiveness that there was a fair, more
23 or less an equivalence in terms of effectiveness.

24 Q. Do you remember what their safety

1 numbers showed?

2 A. I don't recall specifically how the
3 safety metrics were broken down, nor if there was
4 discernment made between mesh specific and/or nonmesh
5 specific safety metrics.

6 Q. Okay. Is there any reason to think that
7 Dr. Diamond did not know essentially what you believe
8 you knew in 2007 about the risks of these procedures?

9 A. I couldn't offer that opinion, no.

10 Q. In your Case Specific Opinion Number 1
11 you talk about that the vaginal pain and voiding
12 dysfunction were caused by scarring following the TVT
13 device.

14 Do you see that?

15 A. That's correct.

16 Q. First of all, how would midurethral
17 sling that is not inside the urethra or inside the
18 bladder cause urinary tract infections or make them
19 more severe? What's the physical connection?

20 A. Well, urinary incontinence can certainly
21 be a risk factor for urinary tract infections, and her
22 urinary incontinence has persisted, in a certain sense
23 has worsened.

24 Q. Okay. Is that the only plausible

1 connection?

2 A. I also offered opinions that her
3 dysfunctional voiding is in part related to the TVT-O
4 sling. In theory, if patients are retaining urine,
5 that could be an additional risk factor.

6 Q. But there's no evidence that she is,
7 correct?

8 A. The only evidence that she is is
9 rendered by Dr. Wilks in his last evaluation of this
10 patient.

11 Q. Did he have any studies to indicate? I
12 mean, you can do studies to see if she's retaining,
13 correct?

14 A. Yes, he did a post void residual check
15 on this patient that indicated a post void residual of
16 50 CCs.

17 Q. That would not rise to the level, no pun
18 intended, of retention, would it?

19 A. I wouldn't call that retention, no, sir.

20 Q. Is there any objective evidence of
21 scarring as the cause of the dysfunction or any pain,
22 an x-ray, an ultrasound, a pathology finding, anything?

23 A. Nothing of that nature.

24 Q. Is there some other objective, a

1 physical exam finding, for example?

2 A. There's no physical exam finding
3 memorialized that documents midurethral pain, for
4 example.

5 Q. All right. So there is no evidence in
6 this record objectively on a physical exam or some sort
7 of a test that she actually has scarring that is
8 clinically significant from her TVT-O, correct?

9 A. Yeah, the conclusions are really drawn
10 based on subjective findings and inference.

11 Q. Her subjective findings, in other words,
12 the history she gives?

13 A. Some of her subjective complaints that
14 were memorialized by some of her examining doctors,
15 yes.

16 Q. And many of those subjective complaints
17 or all of them, I don't have time to go back through
18 all of them, do have other potential explanations for
19 them, correct?

20 A. Well, with the exception of some of her
21 obstructive voiding symptoms, I would agree with you.
22 The obstructive voiding systems being intermittency,
23 straining, spraying of stream and hesitancy.

24 Q. Did Dr. Wilks ever indicate a guarded

1 prognosis in his records?

2 A. No, not to my recollection.

3 Q. Down towards the end of your report, it
4 mentions she's not an ideal candidate for this type of
5 surgery and is likely best treated with medical therapy
6 in combination with lifestyle modification and pelvic
7 floor physiotherapy.

8 Do you see that?

9 A. I do.

10 Q. Now, from the records and her deposition
11 testimony, has she shown the willingness, the interest
12 and the sticktuitiveness to alter her lifestyle in the
13 ways that you suggest here?

14 A. I don't believe so.

15 MR. MORIARITY: Let me take a break. Go
16 through my last notes.

17 I'll reserve my five minutes.

18 BY MR. THOMPSON:

19 Q. Doctor, I know we've been kind of hard
20 on Ms. Pridmore, but let's point out this record, and I
21 don't have the actual number, I think it was 9 and 10.
22 Its an encounter of 9/27/2012.

23 MR. MORIARITY: Those are the Slotar
24 notes.

1 BY MR. THOMPSON:

2 Q. Look at Page 2 of 4?

3 A. Exhibit 16.

4 Q. If I turn to Page 2 and look down here,
5 there's something that says "Vitals."

6 A. Yes.

7 Q. You see that?

8 A. I do.

9 Q. And if I look and I see April 12, 2012,
10 I see her weight is 302 pounds?

11 A. Yes.

12 Q. Then if I look on September 27, 2012,
13 her weight is 277.

14 You see that?

15 A. I do.

16 Q. So Ms. Pridmore, despite this cornucopia
17 of complaints and physical conditions, Ms. Pridmore
18 hasn't given up, she lost 25 pounds, didn't she?

19 A. Yes.

20 Q. She is trying at least?

21 A. It would seem that way, yes.

22 Q. Now, Doctor, with regard to your report,
23 you have gone through and it's been pointed out that
24 there are missing records from earlier on

1 Ms. Pridmore's course. You've gone through a variety
2 of documents and medical reports.

3 Have you seen any documents or any
4 medical records that cause you to withdraw or abandon
5 any of the opinions that you express in your report?

6 A. No, I do not.

7 Q. And, Doctor, I understand that you have
8 answered that it would be very helpful and useful to
9 have earlier medical records. Does the absence of
10 those records make it impossible for you apply
11 techniques of differential diagnosis to arrive at your
12 conclusions?

13 A. No, it does not.

14 Q. Doctor, do you hold these opinions to a
15 reasonable medical certainty?

16 A. I do.

17 MR. THOMPSON: Thank you very much.

18 That's it for me.

19 BY MR. MORIARITY:

20 Q. Couple follow-up questions.

21 General Opinion Number 2 say for
22 alternative design and procedures.

23 A. Yes.

24 Q. Tell me what they were in 2007.

1 A. One was the autologous fascial sling.
2 In fact, that's really the only one that I would put
3 forth in here today.

4 Q. And what Level 1 evidence do you rely on
5 to say that that has a lesser risk of pelvic pain and
6 scarring?

7 A. In my own practice and my review of the
8 literature and my training, I have not encountered the
9 same types of risks inherent to the use of synthetic
10 vaginal mesh that I would to using something that's
11 nonmesh-based as far as my repair.

12 Q. Do you know of any randomized controlled
13 trials or other published literature supporting the
14 proposition that autologous fascial slings have less
15 risk of pain and scarring than synthetic midurethral
16 slings?

17 A. Well, I think there are two trials that
18 you might have even alluded to that are not in my
19 reliance list that would speak to that. One being the
20 Tomas trial and the other being the Kahn article that
21 points to substantial efficacy in the absence of
22 mesh-specific complications.

23 Q. They do have complications, right?

24 A. They do.

1 Q. So what we're down to is whether the
2 complication is caused by mesh or something else, you
3 have to compare the pain rates, for example, in those
4 trials, right?

5 A. Correct.

6 Q. IFUs, last thing I want to ask you
7 about. Do you read the IFU for any products that you
8 use every time you operate?

9 A. Not every time I operate, no.

10 Q. How much do you rely on the IFU to
11 convey potential risks and complications of a
12 procedure?

13 A. I provide liberal weight to the IFU when
14 I'm consenting patients, particularly when I'm first
15 using a procedure or device, performing a procedure,
16 using a device to execute a procedure.

17 Q. I don't know what you mean by liberal
18 weight.

19 A. I rely upon it heavily more so in the
20 infancy of me using a device for a procedure.

21 Q. Okay. After you've used it, you rely
22 less on the IFU?

23 A. I don't look at it as often, typically
24 because IFUs don't often change or evolve over time.

1 Q. What does change and evolve over time is
2 the continuing -- I'm sorry -- the published medical
3 literature, correct?

4 A. There is a dynamic there, yes.

5 Q. That's what gives you as a practitioner
6 and a teacher of these residents the most up-to-date
7 information about efficacy and safety, correct?

8 A. I think especially as it relates --
9 yeah, I think for both those metrics that's true for
10 both efficacy and safety.

11 Q. And continuing medical education as
12 well, you go to seminars where these things are
13 discussed, right?

14 A. I do.

15 Q. And your colleagues from across the
16 country are speaking about the most recent information
17 about risks, complications, efficacy, correct?

18 A. Yes.

19 Q. And you absorb that and take it into
20 account as well as the IFU; is that right?

21 A. I do.

22 MR. MORIARITY: I think I've probably
23 used all my time and your patience.

24 (Witness excused.)

1 (Deposition concluded at 6:13 p.m.)

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C E R T I F I C A T I O N

I, MARGARET M. REIHL, a Registered Professional Reporter, Certified Realtime Reporter, Certified Shorthand Reporter, Certified LiveNote Reporter and Notary Public, do hereby certify that the foregoing is a true and accurate transcript of the testimony as taken stenographically by and before me at the time, place, and on the date hereinbefore set forth.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

Margaret M. Reihl, RPR, CRR, CLR

CSR #XI01497 Notary Public

Konstantin Walmsley, M.D.

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4 PAGE LINE CHANGE

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Konstantin Walmsley, M.D.

1 ACKNOWLEDGMENT OF DEPONENT

2

3 I, KONSTANIN WALMSLEY, M.D., do hereby
4 certify that I have read the foregoing pages,
5 and that the same is a correct transcription of
6 the answers given by me to the questions
7 therein propounded, except for the corrections
8 or changes in form or substance, if any, noted
9 in the attached Errata Sheet.

10

11

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13 _____
KONSTANTIN WALMSLEY, M.D. DATE

14

Subscribed and sworn to before me this

15

_____ day of _____, 2016.

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My commission expires:_____

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Notary Public

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